

AGENDA
CIRCULATORY SYSTEM DEVICES PANEL

July 28, 2004

Holiday Inn, Grand Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

9:00 – 5:00			PMA Discussion, Recommendations, and Voting
9:00 a.m.	Call to Order		Warren Laskey, M.D.
			Acting Chairperson
9:05 – 9:30 a.m.	*Open Public Session*		
9:30 – 10:45 a.m.	Sponsor Presentation: Guidant Corporation		
	P010012/S26: Guidant Cardiac Resynchronization Therapy Defibrillators (CRT-Ds)		
10:45 – 11:00 a.m.	Questions and Answers		
11:00 – 11:15 a.m.	Break		
11:15 – 12:15 p.m.	FDA Presentation		
12:15 – 12:30 p.m.	Questions and Answers		
12:30 p.m.	Adjourn – Break for Lunch		
1:30 p.m.	Call to Order		
1:30 – 3:45 p.m.	Open Committee Discussion		Warren Laskey, M.D.
3:45 – 4:00 p.m.	Break		
4:00 – 5:00 p.m.	*Open Public Session*		
	FDA Comments		
	Sponsor Comments		
	Recommendations & Vote		Warren Laskey, M.D.
5:00 p.m.	Adjourn		

OPEN PUBLIC HEARINGS*

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.

Ms. Wood will present the speakers who have requested time for presentation to the Panel. After the scheduled speakers have spoken, the Chair may ask them to remain if the committee wishes to question them further. Dr. Laskey will recognize unscheduled speakers as time allows.

Note: Only the Chair and members of the Panel may question speakers during the open public hearing.